



DEPARTMENT OF HEALTH AND HUMAN SERVICES

91260d
Food and Drug Administration
Kansas City District
Southwest Region
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

May 14, 2001

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER

Ref. KAN #2001-023

Fred W. Howard, President
Ozark Country Foods, Inc.
10923 State Highway 176
Walnut Shade, MO 65771

Dear Mr. Howard:

During an inspection of your firm on March 8-12, 2001, we reviewed your revised labels for Sassafras jelly. This label continues to misbrand the food under Section 403(k) of the Federal Food, Drug, and Cosmetic Act (the Act) because your Sassafras jelly contains natural and artificial Sassafras flavor and the presence of the artificial flavor is not declared on the label. In addition, while you revised your Sassafras Jelly label to declare the addition of red food coloring your label is still not correct. Section 403(i) of the Act and Title 21 Code of Federal Regulations (21 CFR) Part 101.22 control the declaration of certified colors on food labels. The ingredient "Red Food Color" contains the certified colors Red 40 and Blue 1. The certified colors must be declared in the ingredient statement by their common or usual name (e.g., Red 40, Blue 1).

Your Corn Cob Jelly is misbranded under Section 403(i)(2) of the Act because it contains the certified colors Yellow 6 (from Egg Shade), and Red 40 and Blue 1 (from Red Food color) which are not declared on the label in accordance with 21 CFR 101.22.

We further point out that while you revised your Cherry Jam label to declare the addition of red food coloring, Cherry Jam is a standardized food. The standard of identify [21 CFR 150.160] does not provide for the addition of color to Cherry Jam.

Additionally, we observed that an acidified food, "Total Garden Salsa" is processed at your facility. Our investigator's observations revealed deviations from Good Manufacturing Practice (GMP) regulations for acidified foods (21 CFR 114), and Emergency Permit Control regulations (21 CFR 108.25). These deviations cause your "Total Garden Salsa" to be

adulterated within the meaning of Section 402(a)(4) of the Act. The deviations found during the inspection include:

Your firm did not have sufficient control, including adequate pH testing to ensure that finished equilibrium pH for salsa always met that of the scheduled process [21 CFR 114.80(a)(2)].

The letter that you provided from your processing authority that established your process for producing salsa lacked minimum process time and temperature values and product formulation specifications [21 CFR 108.25(c)(3)(ii)].

Your firm did not mark each container with an identifying code specifying the lot number or period during which it was packed [21 CFR 114.80(b)].

Your firm's operators of processing and packaging systems were not under the supervision of a person who has attended a school approved by the Commissioner for giving instruction in food plant sanitation practices, pH controls and critical factors in acidification [21 CFR 108.25(f) and 114.10].

Your firm did not prepare and maintain a current procedure for recalling products under their control and for implementing recall programs should the need arise [21 CFR 108.25(e)].

The above is not intended to be an all-inclusive list of deficiencies at your facility. As a manufacturer of acidified foods, and other food products, you are responsible for assuring that products you produce and distribute are in compliance with the law. This includes reviewing your other food product labels for conformity with labeling regulations.

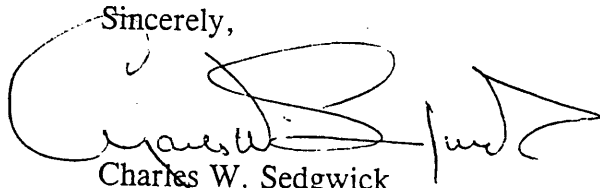
You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or obtaining a court injunction against further marketing of your food products.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent these violations from happening again. If you need more time, let us know why and when you expect to complete your correction.

Fred W. Howard, President
Ozark Country Foods, Inc.
May 14, 2001
Page 3

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles W. Sedgwick", with a large, stylized flourish extending to the right.

Charles W. Sedgwick
District Director
Kansas City District